

REMARKS

Herewith, claims 11, 38 and 52-58 are canceled and claims 1-3, 12, 13, 24-26, 39 and 40 are amended to correct claim dependency, claim syntax, and/or antecedent basis and/or to be in compliance with U.S. practice. Thus, pursuant to the entry of the instant amendment, claims 1-10, 12-37, and 39-51 are presently pending. Applicants respectfully submit that the present amendment should not be construed as a narrowing amendment presented for the purposes of patentability.

So as to be deemed responsive to the restriction and election of species requirements set forth in the Office Action of January 5, 2009, Applicants herewith provisionally elect **with traverse** the invention of **Group II**, drawn to a method for preserving the endothelium of hollow organs, namely **blood vessels**, that utilizes a composition comprising (a) a physiological electrolyte solution, (b) a homologous anti-coagulatory-acting blood plasma preparation, and (c) a nutrient substrate, the invention encompassing claims 1, 3-5, 12-13, and 20-22. Accordingly, claims 2, 6-10, 14-19, 23-37, and 39-51 stand provisionally withdrawn from consideration.

However, Applicants respectfully submit that the convoluted and cumbersome restriction requirement set forth in the previous office action is improper, in whole or in part. Furthermore, Applicants respectively submit that the division of the present invention into innumerable distinct species is unduly restrictive and therefore constitutes an undue burden on Applicants. Accordingly, Applicants petition for review and reconsideration of the restriction in view of the following remarks:

Restriction:

In the Office Action of January 5, 2009, the Examiner requested that Applicants elect one from among twenty-two (22) narrowly defined categories of invention. The Examiner alleges that restriction is necessitated by the multiple “diverting points” set forth in both the method and composition claims. However, Applicants respectfully submit that the dependent claims do not “divert” but rather further define and/or clarify components or steps previously recited. For example, the Examiner suggests that the methods of claims 8, 9, and 10 correspond to distinct inventive groups III, IV, and V, respectively. However, dependent claim 8-10, in accordance with conventional practice, merely further define the physiological electrolyte solution of claim 1 as either selected from about 2-10 mM glucose and about 1-10 mM pyruvate (claim 8), selected from about 0.1-0.6 U/ml heparin, about 50-100 μ M of uric acid and about 50-100 μ M of ascorbate (claim 9) or comprised of 100-150 mM NaCl; about 1-15 mM KCl; about 0.1-4 mM MgSO_4 ; about 0.5-2 mM KH_2PO_4 ; about 24-48 mM histidin-Cl and about 1-3 mM CaCl_2 (claim 10). Thus, contrary to the Examiner’s suggestion, Applicants use of dependent claims to set out specific alternative preferred embodiments is neither improper nor necessitating a burdensome restriction. What is in fact improper is requiring an Applicant to limit his claims to one particularly preferred embodiment, to the exclusion of other related embodiments all of which fall within the scope of a novel generic invention.

The Examiner further argues in favor of restriction by asserting that the inventions of Groups I – XXII do not relate to a single general inventive concept because they lack the same or corresponding special technical features that define over the art. In support of this assertion, the Examiner cites to published international application WO 2002/35929 as allegedly disclosing the composition as claimed, comprising a physiological electrolyte solution, at least 0.1% native albumin, and a nutrient substrate. However, Applicants respectfully submit that the WO 2002/35929 publication fails to disclose the perfusion solution as presently claimed, nor does it disclose Applicants’ claimed method and apparatus for using same. Accordingly, it cannot

negate the distinguishing nature of the shared technical features or establish a lack of unity. Furthermore, Applicants wish to remind the Examiner that unity of invention is to be considered only in relation to the independent claims and not the dependent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art.

For these reasons, Applicants respectfully submit that it is improper to categorize the various dependent claims into distinct “groups of invention”.

Election of Species:

In addition to the cumbersome restriction requirement set out above, the Examiner further instructed Applicants to elect one from among the various “hollow organs” claimed. The Examiner alleges that the search and examination of these “patentably distinct species” would be unduly burdensome, given their mutually exclusive characteristics. As mentioned above, in order to be deemed responsive, Applicants provisionally elect with traverse the species of blood vessels. However, Applicants petition for review and reconsideration of the restriction in view of the following remarks:

It is well settled that if the members of a Markush group (e.g., the alternative organ systems recited in claim 20) are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they may be directed to independent and distinct inventions. Moreover, restriction among groups within a Markush claim is *per se* improper if it can be shown that the members of the Markush group share (a) a common utility and (b) a substantial structural feature essential to that utility. In this case, Applicants respectfully submits that the Markush members set forth in claim 20 are so few in number and interrelated that no serious burden would be imposed upon the examiner to search the entirety of the claims.

Furthermore, as noted above, it is well settled that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, in its entirety, even though it may include claims to distinct or independent inventions. In this case, it is readily apparent that the search for one species would necessarily overlap with that required for the other claimed species. Accordingly, it appears that search and examination of all species would not constitute an undue burden on the Examiner. What is in fact an “undue burden” is requiring an Applicant to file multiple divisional applications, and ultimately pay multiple issue and maintenance fees, to obtain protection to a single novel generic invention.

Rejoinder:

In the event the Examiner maintains the outstanding restriction between the elected preservation methods set forth in claims 1, 3-5, 12-13, and 20-22 and the remaining preservation methods in claims 2, 6-10, and 14-19 and/or the perfusion solutions and apparatus useful therewith as set forth in claims 24 *et seq.*, and 47 *et seq.*, respectively, Applicants reserve the right to present any non-elected claims in one or more divisional applications. Applicants further reserve the right of rejoinder in accordance with the provisions of 37 C.F.R. § 1.104. To that end, Applicants wish to remind the Examiner that upon the allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim. In particular, once a generic claim is allowable, all of the claims drawn to species in addition to the elected species which require all the limitations of the generic claim will ordinarily be allowable over the prior art in view of the allowability of the generic claim, since the additional species will depend thereon or otherwise require all of the limitations thereof. M.P.E.P. § 806.04(d). Accordingly, the examination of non-elected method, product and apparatus claims should be held in abeyance until the indication of an allowable method claim.

Likewise, in the event that the Examiner insists on maintaining the instant election of species requirement, Applicants hold in abeyance the examination of the additional species upon an indication of allowability of the elected species pursuant to M.P.E.P. § 803.02. In particular, it is noted that "should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended [to the non-elected species]. . . The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim." M.P.E.P. § 803.02. Thus, Applicants await the Examiner's findings and the extension of the prior art search to include species of hollow organs other than blood vessels.

CONCLUSION

The outstanding Office Action set a one-month shortened statutory period for response. In that Applicants submit herewith a Petition for a Three-Month Extension of Time, the deadline for response is **May 5, 2009**. Thus, Applicant submits that this response is timely and no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

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